

UNITED STATES DISTRICT COURT

DISTRICT OF NEW MEXICO

RUBEN GRIEGO,

Plaintiff,

V.

TORRENT PHARMACEUTICALS LTD.;
CAMBER PHARMACEUTICALS, INC.;
TEVA PHARMACEUTICALS USA, INC.;
MACLEODS PHARMACEUTICAL LTD.;
PD-RX PHARMACEUTICALS, INC.;
SANDOZ INC.; JOHN AND JANE DOES 1-
10; AND ENTITIES, CORPORATIONS,
AND PARTNERSHIPS 1-10.

Defendants.

CASE NO. 1:22-cv-00663--JFR-SMV

DEFENDANT PD-RX PHARMACEUTICALS, INC.'S
ANSWER TO PLAINTIFF'S COMPLAINT

COMES NOW PD-RX Pharmaceuticals, Inc. (“Defendant”) and files this Answer to Plaintiff’s Complaint:

I. PARTIES, JURISDICTION, AND VENUE

1. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 1 of the Complaint, and therefore denies them.

2. The allegations contained in paragraph 2 are directed against another defendant, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or

information sufficient to form a belief as to the allegations of Paragraph 2 of Plaintiff's Complaint.

3. The allegations contained in paragraph 3 are directed against another defendant, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 3 of Plaintiff's Complaint.

4. The allegations contained in paragraph 4 are directed against another defendant, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 4 of Plaintiff's Complaint.

5. The allegations contained in paragraph 5 are directed against another defendant, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 5 of Plaintiff's Complaint.

6. The allegations contained in paragraph 6 are directed against another defendant, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 6 of Plaintiff's Complaint.

7. Defendant admits that it is an Oklahoma corporation with its principal place of business in Oklahoma. Defendant denies any remaining or inconsistent allegations in Paragraph 7 of Plaintiff's Complaint.

8. The allegations contained in paragraph 8 are directed against another defendant, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 8 of Plaintiff's Complaint.

9. Defendant admits that in 2019-2020 it distributed Losartan in New Mexico. Defendant denies knowledge or information sufficient to form a belief as to the remaining allegations of Paragraph 9 of Plaintiff's Complaint directed to other defendants.

10. The allegations contained in paragraph 10 are directed against other entities, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 10 of Plaintiff's Complaint.

11. The allegations contained in paragraph 11 are directed against other entities, and therefore no response is necessary. If response is necessary, Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 11 of Plaintiff's Complaint.

12. Defendant is without knowledge or information sufficient to form a belief as to the truth of the allegations in paragraph 12 of the Complaint, and therefore denies them.

13. Defendant states that the allegations in paragraph 13 are legal conclusions to which no response is necessary. If response is necessary, Defendant denies that this Court has jurisdiction over Defendant and further denies the remaining allegations of Paragraph 13 of Plaintiff's Complaint.

14. Defendant states that the allegations in paragraph 14 are legal conclusions to which no response is necessary. If response is necessary, Defendant denies that this Court is a proper venue and denies the remaining allegations of Paragraph 14 of Plaintiff's Complaint.

II. STRICT LIABILITY (DESIGN DEFECT)

15. Defendant incorporates by reference its responses to all prior allegations of Plaintiff's Complaint as if the same were fully set forth at length herein.

16. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant denies the remaining allegations of Paragraph 16 of Plaintiff's Complaint.

17. Defendant denies the allegations in paragraph 17 of the Complaint.

18. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant denies any remaining allegations of Paragraph 18 of Plaintiff's Complaint.

19. Defendant denies the allegations of Paragraph 19 of Plaintiff's Complaint.

20. Defendant denies the allegations of Paragraph 20 of Plaintiff's Complaint.

21. Defendant denies the allegations of Paragraph 21 of Plaintiff's Complaint.

22. Defendant denies the allegations of Paragraph 22 of Plaintiff's Complaint, including all subparts.

23. Defendant denies the allegations of Paragraph 23 of Plaintiff's Complaint.

24. Defendant denies the allegations of Paragraph 24 of Plaintiff's Complaint.

25. Defendant denies the allegations of Paragraph 25 of Plaintiff's Complaint.

26. Defendant denies the allegations of Paragraph 26 of Plaintiff's Complaint.

27. Defendant denies the allegations of Paragraph 27 of Plaintiff's Complaint.

28. Defendant denies the allegations of Paragraph 28 of Plaintiff's Complaint.

29. Defendant denies the allegations of Paragraph 29 of Plaintiff's Complaint.

30. Defendant denies the allegations of Paragraph 30 of Plaintiff's Complaint.

31. Defendant denies the allegations of Paragraph 31 of Plaintiff's Complaint.

32. Defendant denies the allegations of Paragraph 32 of Plaintiff's Complaint.

33. Defendant denies the allegations of Paragraph 33 of Plaintiff's Complaint.

34. Defendant denies that Plaintiff is entitled to judgment or any relief requested, and denies the remaining allegations of paragraph 34.

III. STRICT LIABILITY (FAILURE TO WARN)

35. Defendant incorporates by reference its responses to all prior allegations of Plaintiff's Complaint as if the same were fully set forth at length herein.

36. Defendant denies the allegations of Paragraph 36 of Plaintiff's Complaint.

37. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant denies any remaining allegations of Paragraph 37 of Plaintiff's Complaint.

38. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant denies any remaining allegations of Paragraph 38 of Plaintiff's Complaint.

39. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant states that the allegations in this paragraph regarding duty constitute a legal conclusion to which no response is required. To the extent a response is required, Defendant admits that it complied with its duty under the law at all times. Defendant denies any remaining allegations of Paragraph 39 of Plaintiff's Complaint.

40. Defendant states that the allegations in this paragraph regarding duty constitute a legal conclusion to which no response is required. To the extent a response is required,

Defendant admits that it complied with its duty under the law at all times. Defendant denies the remaining allegations of Paragraph 40.

41. Defendant denies the allegations of Paragraph 41 of Plaintiff's Complaint.

42. Defendant denies the allegations of Paragraph 42 of Plaintiff's Complaint.

43. Defendant denies the allegations of Paragraph 43 of Plaintiff's Complaint.

44. Defendant denies the allegations of Paragraph 44 of Plaintiff's Complaint.

45. Defendant admits that in 2019-2020 it distributed losartan in New Mexico.

Defendant denies any remaining allegations of Paragraph 45 of Plaintiff's Complaint.

46. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 46 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 46 of Plaintiff's Complaint.

47. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 47 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 47 of Plaintiff's Complaint.

48. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 48 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 48 of Plaintiff's Complaint.

49. Defendant denies the allegations in paragraph 49 of Plaintiff's Complaint.

50. Defendant denies the allegations in paragraph 50 of Plaintiff's Complaint.

51. Defendant denies the allegations in paragraph 51 of Plaintiff's Complaint.

52. Defendant denies the allegations in paragraph 52 of Plaintiff's Complaint.

53. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 53 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 53 of Plaintiff's Complaint.

54. Defendant denies the allegations in paragraph 54 of Plaintiff's Complaint.

55. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 55 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 55 of Plaintiff's Complaint.

56. Defendant denies that Plaintiff is entitled to judgment or any relief requested, and denies the remaining allegations of paragraph 56.

IV. NEGLIGENCE

57. Defendant incorporates by reference its responses to all prior allegations of Plaintiff's Complaint as if the same were fully set forth at length herein.

58. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant denies any remaining allegations of Paragraph 58.

59. Defendant states that the allegations in this paragraph regarding duty constitute a legal conclusion to which no response is required. To the extent a response is required, Defendant admits that it complied with its duty under the law at all times. Defendant denies the remaining allegations of Paragraph 59 of Plaintiff's Complaint.

60. Defendant states that the allegations in this paragraph regarding duty constitute a legal conclusion to which no response is required. To the extent a response is required, Defendant admits that it complied with its duty under the law at all times. Defendant denies the remaining allegations of Paragraph 60 of Plaintiff's Complaint.

- 61. Defendant denies the allegations in paragraph 61 of Plaintiff's Complaint.
- 62. Defendant denies the allegations in paragraph 62 of Plaintiff's Complaint.
- 63. Defendant denies the allegations in paragraph 63 of Plaintiff's Complaint.
- 64. Defendant denies the allegations in paragraph 64 of Plaintiff's Complaint.
- 65. Defendant denies the allegations in paragraph 65 of Plaintiff's Complaint.
- 66. Defendant denies the allegations in paragraph 66 of Plaintiff's Complaint.
- 67. Defendant denies the allegations in paragraph 67 of Plaintiff's Complaint, including all subparts.
- 68. Defendant denies the allegations in paragraph 68 of Plaintiff's Complaint.
- 69. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 69 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 69 of Plaintiff's Complaint.
- 70. Defendant denies the allegations in paragraph 70 of Plaintiff's Complaint.
- 71. Defendant denies the allegations in paragraph 71 of Plaintiff's Complaint.
- 72. Defendant denies the allegations in paragraph 72 of Plaintiff's Complaint.
- 73. Defendant denies the allegations in paragraph 73 of Plaintiff's Complaint.
- 74. Defendant denies that Plaintiff is entitled to judgment or any relief sought, and denies the remaining allegations of paragraph 74.

V. BREACH OF EXPRESS WARRANTY

- 75. Defendant incorporates by reference its responses to all prior allegations of Plaintiff's Complaint as if the same were fully set forth at length herein.

76. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant denies the remaining allegations of Paragraph 76 of Plaintiff's Complaint.

77. Defendant states that the allegations in this paragraph regarding duty constitute a legal conclusion to which no response is required. To the extent a response is required, Defendant admits that it complied with its duty under the law at all times. Defendant denies the remaining allegations of Paragraph 77 of Plaintiff's Complaint, including all subparts.

78. Defendant states that the allegations in this paragraph constitute a legal conclusion to which no response is required. To the extent a response is required, Defendant admits that it complied with its duty under the law at all times. Defendant denies the remaining allegations of Paragraph 78 of Plaintiff's Complaint.

79. Defendant denies the allegations in paragraph 79 of Plaintiff's Complaint.

80. Defendant denies the allegations in paragraph 80 of Plaintiff's Complaint.

81. Defendant states that the allegations in this paragraph constitute a legal conclusion to which no response is required. If a response is required, Defendant denies the allegations of Paragraph 81 of Plaintiff's Complaint.

82. Defendant admits that in 2019-2020 it distributed losartan in New Mexico. Defendant denies any remaining allegations of Paragraph 82 of Plaintiff's Complaint.

83. Defendant denies the allegations of Paragraph 83, including all subparts.

84. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 84 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies any remaining allegations of Paragraph 84.

85. Defendant denies the allegations of Paragraph 85 of Plaintiff's Complaint.

86. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 86 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies any remaining allegations of Paragraph 86 of Plaintiff's Complaint.

87. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 87 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies any remaining allegations of Paragraph 87 of Plaintiff's Complaint.

88. Defendant denies the allegations of Paragraph 88 of Plaintiff's Complaint.

89. Defendant denies the allegations of Paragraph 89 of Plaintiff's Complaint.

90. Defendant denies the allegations of Paragraph 90 of Plaintiff's Complaint.

91. Defendant denies that Plaintiff is entitled to judgment or other relief sought, and denies the remaining allegations of paragraph 91 of Plaintiff's Complaint.

VI. BREACH OF IMPLIED WARRANTIES

92. Defendant incorporates by reference its responses to all prior allegations of Plaintiff's Complaint as if the same were fully set forth at length herein.

93. Defendant denies the allegations of Paragraph 93.

94. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 94 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 94 of Plaintiff's Complaint.

95. Defendant denies the allegations of Paragraph 95 of Plaintiff's Complaint.

96. Defendant denies the allegations of Paragraph 96.

97. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 97 as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 97 of Plaintiff's Complaint.

98. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 98 of Plaintiff's Complaint as to Plaintiff's use of losartan. Defendant denies any remaining allegations of Paragraph 98.

99. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 99 as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 99.

100. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 100 as to Plaintiff's use of losartan. Defendant denies any remaining allegations of Paragraph 100 of Plaintiff's Complaint.

101. Defendant denies knowledge or information sufficient to form a belief as to the allegations of Paragraph 101 as to Plaintiff's use of losartan. Defendant denies the remaining allegations of Paragraph 101 of Plaintiff's Complaint.

102. Defendant denies the allegations of Paragraph 102 of Plaintiff's Complaint.

103. Defendant denies the allegations of Paragraph 103 of Plaintiff's Complaint.

104. Defendant denies the allegations of Paragraph 104 of Plaintiff's Complaint.

105. Defendant denies the allegations of Paragraph 106 of Plaintiff's Complaint.

106. Defendant denies that Plaintiff is entitled to judgment, damages, or other relief, and denies the remaining allegations of paragraph 106.

JURY TRIAL DEMAND

107. Defendant states that the allegations in this paragraph constitute a legal conclusion to which no response is required. To the extent a response is required, Defendant agrees to a jury demand.

PRAYER FOR RELIEF

Defendant denies that Plaintiff is entitled to any of the items set forth in the prayer for relief. Defendant requests that this Court enter judgment in its favor and against Plaintiff on all counts and allegations of the Complaint and that the Court award Defendant its costs and such other relief as it deems just and proper.

AFFIRMATIVE DEFENSES

1. Plaintiff's claim is barred by the applicable statutes of limitations.
2. Plaintiff's Complaint fails to state a claim upon which relief may be granted.
3. This Court lacks personal jurisdiction over Defendant with respect to Plaintiff's claims, and thus the Complaint should be dismissed under Rule 12(b)(2) of the Federal Rules of Civil Procedure.
4. Plaintiff's claims are preempted in whole or in part by federal and state statutes and regulations.
5. Plaintiff's Complaint should be dismissed insofar as indispensable persons, parties, and entities have not been made parties hereto.
6. Plaintiff's injuries and damages, if any, were caused by the acts and failures to act of persons and/or entities other than the Defendant and for whom the Defendant cannot be held legally liable.

7. The alleged injuries sustained by Plaintiff, if any, were caused, in whole or in part, by pre-existing physical, medical, and/or physiological conditions, for which Defendant has no legal responsibility

8. The injuries and damages sustained by Plaintiff, if any, were caused by the intervening acts or negligence of Plaintiff or one or more unaffiliated third parties for whom the Defendant was not and is not responsible or liable.

9. No act or omission of the Defendant was a cause in fact or a proximate cause of the injuries and damages, if any, sustained by Plaintiff.

10. Plaintiff's own conduct was the cause in fact or proximate cause of the injuries and damages, if any, sustained by Plaintiff.

11. If Plaintiff has sustained injuries or losses as alleged in the Complaint, Plaintiff's claims regarding such injuries or losses may be barred or reduced by Plaintiff's knowingly, voluntarily, and/or willfully assuming the risk of any injury as the result of the consumption of, administration of, or exposure to the product at issue or any medicine or pharmaceutical preparation.

12. At all times pertinent hereto, Defendant's conduct complied with all federal or state statutes or administration regulations existing at the time the product was sold or distributed.

13. The New Drug Application for losartan was approved by the FDA under the applicable statute, 21 U.S.C. § 301 et seq., and regulations promulgated thereunder. Compliance with such statutes and regulations by Defendants demonstrates that losartan was safe and effective and not unreasonably dangerous and, further, preempts and bars Plaintiff's claims.

Compliance with such statutes and regulations also demonstrates that due care was exercised with respect to the design, manufacture, testing, marketing and sale of this prescription drug, and that it was neither defective nor unreasonably dangerous.

14. Plaintiff's claims are barred and/or preempted by federal law because at no time did Defendant have authority to revise or modify the FDA-approved labeling for losartan.

15. At all relevant times, the product at issue was distributed in a reasonable and prudent manner, based upon available medical and scientific knowledge, and further was processed and distributed in accordance with and pursuant to all applicable regulations of the FDA.

16. To the extent Plaintiff's claims are based on alleged misrepresentations or omissions made to the FDA, such claims are barred pursuant to *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

17. Defendant invokes each and every defense available under New Mexico's Law on Product Liability, as detailed in the Restatement (Second) of Torts and Restatement (Third) of Torts as adopted in New Mexico, in New Mexico Civil Jury Instruction Rule 13-1401, et. seq., NMRA 2009, and in relevant decisions by New Mexico courts.

18. The affirmations alleged by Plaintiff were not part of the basis of the bargain, and Defendant will rely upon the rights and defenses accorded to it under the terms and provisions of N.M. Stat. Ann. 1978, § 55-2-313, et seq. and N.M. Stat. Ann. 1978, UJI Civ. 13-1428.

19. Plaintiff's claims are barred in whole or in part because N.M. Stat. Ann. §§ 57-12-1, et seq. exempts conduct expressly permitted by applicable state and federal regulations

20. Plaintiff's claims are barred as a matter of law pursuant to relevant provisions of the Restatement (Third) of Torts and the Restatement (Second) of Torts, including, but not limited, to Section 402A, comment k.

21. Plaintiff's claims are barred, in whole or in part, because the pharmaceutical product at issue provides net benefits for a class of patients within the meaning of Restatement (Third) of Torts: Products Liability § 6 cmt. f.

22. To the extent that the sophisticated purchaser doctrine is applicable to any of the allegations in the Complaint, Defendant intends to rely upon same in defense of this action.

23. Plaintiff's claims are barred in whole or in part by the learned intermediary doctrine. Any warnings which were given were transmitted to the prescribing health care provider; under New Mexico law, the only obligation is to warn the prescribing health care provider, which obligation was fulfilled.

24. Defendant invokes each and every defense available to it under New Mexico's Law on Product Liability, as detailed in the Restatement (Second) of Torts and Restatement (Third) of Torts as adopted in New Mexico, in New Mexico Civil Jury Instruction Rule 13-1401, *et seq.*, NMRA 2009, and in relevant decisions by New Mexico courts.

25. Plaintiff's Complaint fails to state a claim upon which relief can be granted in that the methods, standards, and techniques utilized with respect to the design, manufacture, marketing, and sale of losartan, including adequate warnings and instructions with respect to the product's use included in the product's package insert and other literature, conformed to the applicable state of the art, and the applicable standard of care based upon available medical and scientific knowledge.

26. At all times pertinent hereto, Defendant's conduct conformed to the industry state of the art.

27. At all times pertinent hereto, Defendant exercised such reasonable care and diligence in the performance of its duties as is ordinarily exercised by other entities and/or persons in similar circumstances and under like or similar circumstances.

28. At all times pertinent hereto, any packaging, warnings, labels, or instructions provided by Defendant complied in all respects with applicable federal regulations, thereby resulting in preemption of claims pertaining to these items.

29. Plaintiff's claims regarding warnings and labeling are barred in whole or in part by the doctrine of primary jurisdiction, in that the FDA is charged under law with determining the content of warnings and labeling for prescription drugs.

30. At all times pertinent hereto, the Defendant was not aware, nor reasonably should have been aware, that the product it distributed was hazardous, dangerous or defective or constituted a reasonably foreseeable risk of harm to Plaintiff in the normal and expected use of such product.

31. Any potential dangers associated with the product are inherent in any such product and are no more dangerous than an ordinary consumer would expect.

32. Plaintiff is barred from recovering any damages by virtue of the fact that there was no practical or technically feasible alternative design or formulation that would have prevented the harm alleged by the Plaintiff without substantially impairing the usefulness or intended purpose of the product.

33. Plaintiff voluntarily and knowingly assumed the risk that caused the damages for which Plaintiff claims relief, if any, thereby barring this action and/or reducing Plaintiff's recovery in a proportional manner.

34. As to each cause of action, Plaintiff failed, refused, and neglected to take reasonable steps to mitigate his alleged damages, if any, thus barring or diminishing recovery herein.

35. Plaintiff did not exercise ordinary care, caution, or prudence to avoid the subject incident and his resulting injuries and damages sustained, if any, were directly and proximately caused or contributed to by the fault, carelessness, or negligence of Plaintiff.

36. Plaintiff may have received or may be entitled to receive certain collateral source benefits which act as a set-off to their recovery, if any.

37. Plaintiff's claims for breach of warranty, express or implied, are barred by the applicable provisions of the New Mexico Uniform Commercial Code.

38. Any claim for breach of express warranty must fail because Plaintiff failed to allege any representation about the product at issue giving rise to an express warranty.

39. Any claim for breach of implied warranty fails because the product at issue was used for its ordinary purpose.

40. Any claim for breach of warranty fails because Plaintiff failed to satisfy all conditions precedent or subsequent to the enforcement of such warranty.

41. To the extent that Plaintiff's claims have been settled or Plaintiff will in the future settle with any person or entity with respect to the injuries asserted in the Complaint, the liability of Defendant, if any, should be reduced accordingly.

42. Plaintiff's attempt to collect damages from Defendant based on Plaintiff's alleged injuries caused by a product that Defendant did not manufacture or distribute violates Defendant's rights under the Due Process Clause of the Fifth and Fourteenth Amendments to the United States Constitution; the Takings Clause of the Fifth Amendment of the United States Constitution; the Equal Protection Clause of the Fourteenth Amendment of the United States Constitution; and similar or corresponding provisions of the New Mexico Constitution.

43. Defendant alleges that the Complaint does not describe the alleged actions with sufficient particularity to permit it to ascertain what other defenses may exist at this time. Defendant therefore reserves the right to assert all defenses that may pertain to the Complaint as the facts of the case are discovered.

44. Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

45. Any award of punitive or exemplary damages is barred to the extent that it is inconsistent with the standards and limitations set forth in *BMW of North America, Inc. v. Gore*, 517 U.S. 559 (1996), *State Farm Mutual Automobile Insurance Co. v. Campbell*, 538 U.S. 408 (2003), *Philip Morris USA v. Williams*, 549 U.S. 346 (2007), and *Exxon Shipping Co. v. Baker*, 128 S. Ct. 2605 (2008). Permitting recovery of punitive or exemplary damages in this action would contravene Defendant's rights as reserved by the Fifth, Seventh, Eighth, and Fourteenth Amendments to the United States Constitution and other provisions of the United States Constitution and the New Mexico Constitution.

46. Unless Defendant's liability for punitive damages and the appropriate amount of punitive damages are required to be established by clear and convincing evidence, any award of

punitive damages would violate Defendant's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the New Mexico Constitution, and also would be improper under the applicable state common law and public policies.

47. Plaintiff's claim for punitive damages against Defendant cannot be maintained, because an award of punitive damages would be void for vagueness, both facially and as applied. Among other deficiencies, there is an absence of adequate notice of what conduct is subject to punishment; an absence of adequate notice of what punishment may be imposed; an absence of a predetermined limit, such as a maximum multiple of compensatory damages or a maximum amount, on the amount of punitive damages that a jury may impose; a risk that punitive damages will be imposed retrospectively based on conduct that was not deemed punishable at the time the conduct occurred; and it would permit and encourage arbitrary and discriminatory enforcement, all in violation of the due process clause of the Fourteenth Amendment to the United States Constitution, the New Mexico Constitution, and applicable state common law and public policies.

48. Plaintiffs' claim for punitive damages against Defendant cannot be maintained because any award of punitive damages would be by a jury that: (1) is not provided standards of sufficient clarity for determining the appropriateness, and the appropriate size, of a punitive damages award; (2) is not adequately instructed on the limits on punitive damages imposed by the applicable principles of deterrence and punishment; (3) is not expressly prohibited from awarding punitive damages, or determining the amount of an award of punitive damages, in whole or in part, on the basis of invidiously discriminatory characteristics, including the residence, wealth, and corporate status of Defendant; (4) is permitted to award punitive damages

under a standard for determining liability for punitive damages that is vague and arbitrary and does not define with sufficient clarity the conduct or mental state that makes punitive damages permissible; and (5) is not subject to adequate trial court and appellate judicial review for reasonableness and furtherance of legitimate purposes on the basis of objective standards. Any such verdict would violate Defendant's due process rights guaranteed by the Fourteenth Amendment to the United States Constitution and by the New Mexico Constitution, and also would be improper under applicable state common law and public policies.

49. To the extent that the applicable state law permits punishment to be measured by the net worth or financial status of Defendant and imposes greater punishment on defendants with larger net worth, such an award would be unconstitutional because it permits arbitrary, capricious and fundamentally unfair punishments, allows bias and prejudice to infect verdicts imposing punishment, and allows dissimilar treatment of similarly situated defendants, in violation of the due process and equal protection provisions of the Fourteenth Amendment to the United States Constitution, the Commerce Clause of the United States Constitution, and the New Mexico Constitution.

50. With respect to Plaintiff's demand for punitive or exemplary damages, Defendant specifically incorporates by reference any and all standards or limitations regarding the determination or enforceability of punitive or exemplary damages awards under federal law and the applicable state law.

51. No act or omission of Defendant was willful, unconscionable, oppressive, fraudulent, wanton, malicious, reckless, intentional, or with actual malice, with reckless disregard for the safety of Plaintiff or with conscious disregard and indifference to the rights,

safety and welfare of Plaintiff, and therefore Plaintiff's Complaint fails to state a claim upon which relief can be granted for punitive or exemplary damages.

52. Plaintiff's Complaint seeks damages in excess of those permitted by law. Defendant asserts any statutory or judicial protection from punitive or exemplary damages which is available under the applicable law, and any award of punitive or exemplary damages is barred.

53. Defendant adopts and incorporates by reference herein any affirmative defenses that may be raised by any other Defendant who is in or may be joined to this action.

54. Defendant reserves the right to modify, clarify, amend, or supplement these separate or affirmative defenses as discovery proceeds in this case.

WHEREFORE, Defendant prays as follows:

Plaintiff take nothing by way of his Complaint herein and that this action be dismissed in its entirety; and for such other relief as the Court may deem just and proper.

Dated: September 28, 2022

Respectfully submitted,

GORDON REES SCULLY MANSUKHANI

By: /s/ Kenneth J. Ferguson
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**Attorneys for Defendant
PD-RX Pharmaceuticals, Inc.**

CERTIFICATE OF SERVICE

I hereby certify that on September 28, 2022, I electronically filed the foregoing document with the Clerk of Court using the CM/ECF system, which will send notification of such filing to all attorneys of record.

/s/ Kenneth J. Ferguson
Kenneth J. Ferguson